# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

In re:	04-md-1603 (SHS)
OXYCONTIN ANTITRUST LITIGATION	This document relates to:
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., and PURDUE PHARMACEUTICALS L.P.,	) ) )
Plaintiffs and Counterclaim Defendants,	) Civil Action No.: 1:07 Civ. 03972 (SHS)
v.	, )
KV PHARMACEUTICAL COMPANY and ACTAVIS TOTOWA LLC,	) ) )
Defendants and Counterclaim Plaintiffs,	) )
v.	) )
THE PURDUE FREDERICK COMPANY, THE PURDUE PHARMA COMPANY, and EUROCELTIQUE S.A.,	
Counterclaim Defendants.	) ) )
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., and PURDUE PHARMACEUTICALS L.P.,	) ) ) Civil Action No.: 1:07 Civ. 03973 (SHS)
Plaintiffs and Counterclaim Defendants,	)
v.	Civil Action No. 1:07 Civ. 04810 (SHS) (related)
KV PHARMACEUTICAL COMPANY,	) )
Defendant and Counterclaim Plaintiff,	) THIS DOCUMENT WAS FILED
$\mathbf{v}.$	ELECTRONICALLY VIA CM/ECF
THE PURDUE FREDERICK COMPANY, THE PURDUE PHARMA COMPANY, and EUROCELTIQUE S.A.,	, ) ) )
Counterclaim Defendants.	) JOINT RULE 26(f) REPORT )

Pursuant to Fed. R. Civ. P. 26(f), plaintiffs and counterclaim defendants Purdue Pharma L.P., The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. (collectively "Plaintiffs") and counterclaim defendants The Purdue Frederick Company, The Purdue Pharma Company and Euroceltique S.A. (with Plaintiffs, collectively "Purdue") and defendants and counterclaim plaintiffs KV Pharmaceutical Company ("KV") and Actavis Totowa LLC ("Actavis") (collectively "Defendants") submit this joint report following conference of counsel in which the topics of Fed. R. Civ. P. 26(f) were considered and discussed.

#### **Introduction**

Two of the above-captioned cases (1:07 Civ. 03972 and 1:07 Civ. 03973) were originally filed in the District of Delaware. In response to Plaintiffs' request, on May 1, 2007, the clerk of the Judicial Panel on Multidistrict Litigation ("the Panel") issued a Conditional Transfer Order for these cases such that they would be included with the existing Multidistrict Litigation 1:04-md-01603 ("the OxyContin® MDL"). On May 17, 2007, the deputy clerk of the Panel sent a certified copy of the Conditional Transfer Order to the Clerk for the Southern District of New York and to the Hon. Sidney H. Stein. On May 22, 2007, these two cases were accepted as related cases and associated with the OxyContin® MDL. In addition, Plaintiffs have filed a third lawsuit against KV in this District, 1:07 Civ. 04810 (the "third KV case"), for infringement of the same patents by KV's same proposed generic OxyContin® product (but for a different dosage strength of that product). On June 12, 2007, the Court informed counsel for Purdue that the third KV case has been designated as likewise related to the OxyContin® MDL.

The parties in the above-captioned cases propose that such cases be allowed to proceed in accordance with the schedule and the terms set forth in this Report. While the parties have worked together to agree on a common position for the issues set forth in this Report and

that Fed. R. Civ. P. 26(f) requires be discussed, some disagreements remain. Below, the parties state where they agree, and, where the parties disagree, their respective positions.

#### Nature and Basis of the Claims and Defenses

The parties agree that the instant litigations involve allegations of patent invalidity, patent unenforceability due to inequitable conduct, antitrust violations, and whether these litigations are an exceptional case that entitle any of the parties to recover their attorney's fees.

Plaintiffs have accused KV of infringing U.S. Patent Nos. 5,508,042 (the "042 patent"), 5,549,912 ("the '912 patent") and 5,656,295 ("the '295 patent") (collectively, the "patents-in-suit") in three separate actions. The first two actions, 07 CV 032 and 07 CV 077 directed to KV's 10, 20, 40 and 80 mg dosage forms and KV's 30 and 60 mg dosage forms, respectively, were filed in the District of Delaware. These cases (now 07 CV 03972 and 07 CV 03973) were transferred so as to become part of the OxyContin® MDL. The third action, 07 CV 04810, directed to KV's 15 mg dosage form, was filed in the Southern District of New York. In its Answer and Counterclaims in the instant litigations, KV contends that the patents-in-suit are invalid and unenforceable. KV further contends in each Answer and Counterclaims that Purdue has committed various antitrust violations by engaging in fraud on the Patent Office in procuring the patents-in-suit and by bringing suit against KV on patents which it knows to be invalid and fraudulently obtained. KV has requested a jury trial in all three actions. At this time, KV's only non-infringement contention is that the patents-in-suit are invalid and unenforceable and therefore cannot be infringed.

Plaintiffs have accused Actavis of infringing the '042 patent, the only of the three patents-in-suit that Actavis' Paragraph IV certification references. Actavis has admitted

infringement of that patent. Actavis has asserted that the '042 patent is invalid and unenforceable, and has also asserted antitrust counterclaims.

#### **Possibility For Settlement**

The parties agree that discussions of settlement, if any, should be held at a later time between Purdue and each of the Defendants individually.

#### Exchange of Initial Disclosures Pursuant to Rule 26(a)(1)

The parties agree that Fed. R. Civ. P. 26(a)(1) Initial Disclosures will be made in accordance with the schedule adopted by the Court's Scheduling Order. Purdue and KV propose that Initial Disclosures be exchanged three (3) weeks after the entry of the Scheduling Order.

Actavis proposes that Initial Disclosures be made on a date certain, specifically, June 29, 2007.

#### **Preservation of Discoverable Information**

The parties agree and have taken steps to preserve documents relating to the issues in these cases, including, but not limited to, documents regarding infringement, validity, enforceability, willfulness, antitrust violations and whether these cases are exceptional (including opinions-of-counsel).

#### **Scope of Discovery**

Purdue and Actavis propose that discovery may be taken on Plaintiffs' claims and Defendants' counterclaims of invalidity and unenforceability. Purdue and Actavis further propose that discovery on the remainder of Defendants' counterclaims, including their antitrust-related counterclaims, will remain stayed in accordance with the stay this Court has entered in the OxyContin<sup>®</sup> MDL.

KV proposes that all discovery and proceedings be stayed except for any proceedings related to the inequitable conduct claims until the Court decides the issue of

inequitable conduct. However, in the alternative, if the Court orders that discovery go forward, KV proposes that discovery be taken on <u>all</u> of Plaintiffs' claims and Defendants' counterclaims, i.e., Defendants' counterclaims directed to invalidity, unenforceability and Defendants' antitrust-related counterclaims.

The parties agree that fact discovery for all the litigations shall commence one (1) week after the Court has entered a Scheduling Order if the Court does not adopt KV's proposal as set forth above that all discovery and proceedings be stayed except for any proceedings related to the inequitable conduct claims. This will include the third KV case even if the pleadings in that case have not yet been closed.

The parties were unable to reach agreement regarding the case schedule.

Accordingly, set forth below are the parties' respective proposals and additional comments regarding the same, with the caveat that the KV-proposed dates set forth in the table are KV's position only in the event that the Court does not stay all discovery and proceedings except for any proceedings related to the inequitable conduct claims.

Event	STATE OF STA	Actavis Proposal	KV Proposal Patent Claims	KV Proposal Antitrust Claims
Initial disclosures	3 weeks*	6/29/07	3 weeks*	3 weeks*
Production of all materials produced in prior cases	8 weeks		3 weeks	3 weeks
Amendment of pleadings	14 weeks	9/14/07	8 weeks	14 weeks
Joinder of additional parties	14 weeks	9/14/07	8 weeks	14 weeks

<sup>\*</sup> All dates run from the date of entry of the Scheduling Order in these actions.

Event	Purdue	Actavis	KV Proposal	KV Proposal
	Proposal	Proposal	Patent Claims	Antitrust Claims
Last day to rely on the advice-of- counsel defense to rebut a charge of misconduct before the PTO, willful infringement and/or exceptional case, and to produce all opinions-of-counsel and related documents subsumed by the resulting waiver	14 weeks	9/14/07	8 weeks	
Last day to rely on the advice-of- counsel defense to rebut a charge of sham litigation, and to produce all opinions-of-counsel and related documents subsumed by the resulting waiver	Stayed until further order of the Court, pending resolution of patent issues			14 weeks
Service of patent-related contention-seeking interrogatories pursuant to Local Civil Rule 33.3(c)	22 weeks	9/14/07	12 weeks	
Last day for production of all patent-related documents	22 weeks		12 weeks	
Last day for production of all antitrust-related documents	Stayed until further order of the Court, pending resolution of patent issues			16 weeks
Service of antitrust-related contention-seeking interrogatories pursuant to Local Civil Rule 33.3(c)	Stayed until further order of the Court, pending resolution of patent issues			22 weeks
Fact discovery cut-off	32 weeks	11/16/07	16 weeks	36 weeks
Expert reports on issues on which parties bear the burden of proof (with claim charts)	36 weeks	12/21/07	22 weeks	48 weeks
Rebuttal expert reports	40 weeks	1/31/08	28 weeks	52 weeks
Reply expert reports	42 weeks	2/15/08	32 weeks	54 weeks
Expert discovery cut-off	46 weeks	3/14/08	36 weeks	64 weeks
Daubert motions			42 weeks	78 weeks
Daubert oppositions			46 weeks	82 weeks
Summary judgment or other dispositive motions filed	50 weeks	4/14/08	50 weeks	90 weeks

Event	Purdue Proposal	Actavis Proposal	KV Proposal Patent Claims	KV Proposal Antitrust Claims
Oppositions to summary judgment or other dispositive motions	54 weeks	5/14/08	54 weeks	94 weeks
Reply briefs to summary judgment or dispositive motions	56 weeks	5/28/08	56 weeks	96 weeks
Joint pretrial order due	66 weeks	8/1/08	66 weeks	106 weeks
Filings prior to trial due	70 weeks	8/29/08	70 weeks	110 weeks
Final pre-trial conference	72 weeks	9/15/08	72 weeks	112 weeks
Parties ready for trial	74 weeks	9/29/08	74 weeks	114 weeks

### Purdue's Comments Regarding the Schedule

Purdue proposes a schedule that reasonably accommodates all the parties' patent-related claims in accordance with the schedules the Court has adopted in prior OxyContin<sup>®</sup> litigations. Purdue's schedule is based on the Scheduling Order entered by this Court in the *Purdue v. Endo* litigation. (*Endo* D.I. 26).

KV and Actavis, meanwhile, have proposed unfairly short schedules that take advantage of the fact that they will have a significant head start on discovery once they request and receive the extensive discovery (including documents and deposition transcripts) from Purdue's prior OxyContin<sup>®</sup> litigations. Purdue has not yet litigated with KV or Actavis on the patents-in-suit, and will have to start from scratch to develop its cases during discovery. The prejudice caused by Defendants' proposed fact discovery period of only 16 weeks\* will be borne solely by Purdue. Even though Actavis has admitted infringement and KV has not yet contested

<sup>\*</sup> Actavis' position that fact discovery should end on November 16, 2007, assuming the Scheduling Order is entered by mid-July, also provides only an 16-week fact discovery period. The Court has today arranged a scheduling conference for July 12.

infringement, Purdue must still take such discovery relative to, e.g., Defendants' invalidity contentions.

With respect to KV's proposal to stay all issues except for inequitable conduct, Purdue believes that it remains unclear from KV's proposal whether it still intends to seek discovery with respect to inequitable conduct, as set forth in KV's April 18, 2007 letter to the Court, or proceed directly to adjudication on that issue. Indeed, KV has asserted that it cannot ascertain whether it needs additional discovery on inequitable conduct until it reviews the full record from the *Endo* litigation. To the extent that KV still intends to seek discovery with respect to inequitable conduct, Purdue disagrees with KV's proposal. KV is represented in this action by the same counsel who has represented *Boehringer* since 1999. If KV is willing to proceed on the record presented by the *Boehringer* briefing on remand filed in March 2007, and if the Court wishes to proceed with briefing and decision of that issue as the Court ordered in December 2006 in the *Impax* and *Boehringer* cases, based on the *Endo* record, Purdue would agree to that procedure. However, KV appears to want both additional discovery and to derail Purdue's development of its own case. This is fundamentally unfair.

If the parties wish to take additional discovery, then Purdue should be entitled to take the discovery it needs to prepare to try these actions. Furthermore, with regard to KV's alternative schedule, Purdue's position is that the parties should submit "Daubert motions" during the period for filing motions-in-limine, as the Court did in the related *Endo* litigation. Because Purdue and KV propose the same trial-ready date, removing the ten-week, Daubert motion period from KV's alternative schedule provides additional room to adopt Purdue's fact discovery dates.

Contrary to KV's alternative schedule, Purdue's position is that all antitrust-related counterclaims should be stayed in accordance with the Court's March 30, 2006 Order staying all antitrust proceedings in the OxyContin<sup>®</sup> MDL, and the Court's decision to continue that stay at the December 20, 2006 case management conference in the *Impax* and *Boehringer* patent infringement actions.

#### Actavis's Comments Regarding the Schedule

Actavis proposes a streamlined discovery schedule and an early trial date based on Purdue's familiarity with the anticipated issues from prior litigations over the patents in-suit and the nature of the action itself.

As this Court is aware, Purdue has been involved in multiple litigations involving the OxyContin<sup>®</sup> patents asserted in this case. Accordingly, Purdue can quickly and efficiently produce most, if not all of the discovery propounded by Actavis. Moreover, because Actavis has admitted infringement, Purdue need not seek discovery from Actavis concerning this issue.

Importantly, this action also arises under the Hatch-Waxman Act, which requires the parties to "cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii). Each passing day prejudices Actavis's ability to enter the market, as well as the ability of patients to purchase generic drugs at reasonable prices. Accordingly, the discovery and trial schedule proposed by Actavis reflects its desire to expedite this litigation so that it may conclude within a reasonable amount of time.

## KV's Comments Regarding the Schedule

As noted above, KV has filed in each case an Answer And Counterclaims including antitrust counterclaims alleging an overall scheme to monopolize the market for controlled-release oxycodone, including through the commission of Walker Process fraud on the

Patent Office and sham litigation. KV further contends that Purdue committed both inequitable conduct and fraud in the procurement of the asserted patents by withholding material information and making highly material misrepresentations contradicted by Purdue's own material documents and clinical studies.

KV proposes that the Court continue its stay of all discovery and proceedings in the case as the Court has done with other litigations which are a part of or related to the OxyContin<sup>®</sup> MDL except for its determination of whether Purdue committed inequitable conduct in the procurement of the patents-in-suit.

KV submits that this would be the most expeditious scheduling for the Court to adopt since the issue of inequitable conduct is potentially dispositive and since the Federal Circuit has already affirmed this Court's ruling that at least some material information was withheld from the Patent Office by Purdue during patent prosecution. Moreover, proceeding only with the potentially dispositive inequitable conduct issue first will shape the case and potentially avoid unneeded expenditure of resources based on the Court's determination of the inequitable conduct issue.

In the alternative, if the Court declines to adopt KV's position that the stay should be continued, KV submits that full discovery should commence and include all relevant patent, inequitable conduct, and antitrust related materials. Much of the information regarding the patent and antitrust materials are intertwined and found in the same files and many of the witnesses have knowledge of facts relevant to both sets of claims. Not only would a stay of antitrust discovery be inefficient, it would unnecessarily prolong resolution of the important issues raised in this litigation.

#### **Claim Construction**

It is Purdue's position that no further construction of the claims of the patents-insuit is necessary beyond those constructions already issued by this Court or the Federal Circuit in previous litigations. The parties agree that, to the extent that Defendants believe additional claim terms of the patents-in-suit require construction, and the Court engages in such further construction, the parties will present their proposed constructions in connection with summary judgment briefing.

#### **Electronically Stored Information**

Purdue proposes that Purdue's production of electronic documents that were produced in prior litigations will be in the same, non-native format as such prior production.

These electronic documents were produced in a format that is searchable. Production in other formats will likely be burdensome and very expensive.

Purdue further proposes that, for the production of electronic documents that are not contained in a prior production, the parties shall produce such documents in a TIFF format unless the parties otherwise agree on another format for any particular electronic document(s). Metadata shall also be provided for such electronic documents or files, including those attached to e-mails (as well as the emails themselves). For electronic documents or files (e.g., Word, PowerPoint, Excel, etc.), the following metadata shall be provided: Author, Date Created, Date Last Modified, File Name, and File Application. For emails, the following metadata shall be provided: Author, Recipient, CC, BCC, Date Sent, Date Received, Body and Subject or Title.

Actavis proposes that, with respect to the production of electronic documents that are not contained in a prior production, such documents be produced as Group-IV TIFF images.

Actavis also proposes that for email metadata, Time Sent also be included. Purdue has agreed to consider Actavis' proposals and will respond promptly.

KV proposes that all documents be produced in their native formats, not in TIFF format. As such, documents in their native Word, Excel and email formats are already searchable with standard Microsoft software. KV's position is that producing Word, Excel, Outlook emails and the like in their native formats will already provide the metadata pertaining to such documents, to the extent that such data exists.

#### **Limitations on Fact Discovery**

The parties agree that, pursuant to Fed. R. Civ. P. 33(a), interrogatories are limited such that any party may serve a maximum of 25 interrogatories on each adverse party.

Purdue and Actavis propose that, pursuant to Fed. R. Civ. P. 30(a)(2)(A) and 30(d)(2), depositions are limited such that any party may take 10 depositions of each adverse party, and each fact deposition shall be limited to 7 hours. KV proposes that, should discovery go forward on all of Plaintiffs' claims and Defendants' counterclaims, KV be allowed to take 15 depositions. Purdue agrees to allow KV to take 15 depositions if Purdue is likewise allowed to take 15 depositions, all under the same assumption that discovery goes forward on all of Plaintiffs' claims and Defendants' counterclaims (which Purdue opposes).

The parties agree that document requests should not be limited.

Purdue's position is that requests for admission be limited such that any party may serve 50 requests for admission on each adverse party. Defendants' position is that, in accordance with Fed. R. Civ. P. 36, requests for admission should not be limited.

For the purposes of these discovery limits, Purdue's position is that Purdue,

Actavis and KV are each one party, so that the discovery limitations apply to each party as an

absolute limit regardless of the number of cases in which it is a plaintiff, defendant or counterclaim-party.

It is also Purdue's position that Purdue's response to a defendant's discovery request and transcripts of depositions of Purdue witnesses shall not be disclosed, revealed or otherwise made available to the other defendant unless such other defendant joins in the request or the deposition. If the other defendant joins in the request or deposition, then such request or deposition shall be counted against each Defendant in terms of their discovery limits.

Furthermore, it is Purdue's position that with respect to depositions, unless otherwise agreed by the parties, no witness shall be produced for more than one deposition in these cases. However, where it is reasonable to do so, the parties may agree to allow a shared deposition to exceed the seven-hour limitation for depositions.

Purdue notes that the above discovery limitations, however, will not apply to and thus will not limit Defendants' ability to obtain the discovery from Purdue regarding discovery Purdue provided in prior litigations, subject to the entry of a suitable protective order in this case and such orders in prior cases or other confidentiality obligations with respect to the confidential information of third parties. Thus, Purdue states that Defendants will benefit from the extensive document production and deposition testimony and other discovery provided in prior cases. But Defendants should not benefit further from any tactics of pooling their discovery requests to exceed their discovery limitations.

Defendants' position is that Actavis and KV are distinct entities with unique products. Actavis and KV may take different legal positions in this case and may distinctly address a variety of different factual issues. As such, Actavis and KV are entitled to conduct

discovery as separate parties. Purdue should not be allowed to benefit from its litigation tactic of suing Actavis and KV in the same proceeding.

#### **Electronic Service**

The parties agree that service via email to two designated attorneys for a party shall qualify as hand service on the date the email was sent. For such service to Purdue, emails shall be directed to Richard Inz (Richard.Inz@ropesgray.com) and Pablo Hendler (Pablo.Hendler@ropesgray.com). For service to Actavis, emails shall be directed to Jonathan Harris (jah@avhlaw.com) and Chad Landmon (cal@avhlaw.com). For service to KV, emails shall be directed to John F. Sweeney (jsweeney@morganfinnegan.com) and Andrea L. Wayda (awayda@morganfinnegan.com). A party may substitute another attorney or attorneys to receive e-mail service upon written notification to the other parties.

#### **Protective Order**

The parties expect to work together to draft a suitable Protective Order. When final, the parties will submit such Protective Order for consideration and entry by the Court.

Dated: June 13, 2007

s/Richard A. Inz

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# CERTIFICATE OF SERVICE

I hereby certify that on June 13, 2007, I caused to be electronically filed the JOINT RULE 26(F) REPORT with the Clerk of the Court via CM/ECF. Notice of this filing will be sent by e-mail to all parties by operation of the court's electronic filing system. Parties may access this filing through the court's CM/ECF System.

s/Richard A. Inz
Richard A. Inz